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Intellectual Property Dept.
One Health Plaza, Bldg. 104
East Hanover, NJ 07936-1080

In re: Patent Term Extension
Application for
for U.S. Patent No. 7,067,502

REQUIREMENT FOR INFORMATION PURSUANT TO 37 CFR 1.750

This is in response to the application for patent term extension under 35 U.S.C. § 156, filed August 19, 2010 by Novartis AG, the owner of record of U.S. Patent No. 7,067,502 An extension of 926 days is requested.

Pursuant to 37 CFR 1.750, applicant is required to submit the following to the Office:

> Evidence that Novartis AG is authorized by Schering Corporation (now Merck), the owner of U.S. Patent No. 6,068,832, to rely upon the premarket activities of Schering Corporation (now Merck) in seeking extension of U.S. Patent No. 7,067,502.

The above-identified application for patent term extension relies upon the regulatory review for the product DULERA® (mometasone furoate and formoterol fumarate). Exhibit 2 of the present application shows that the holder of New Drug Application (NDA) Nos. 21-518 DULERA® (mometasone furoate and formoterol fumarate) is Schering Corporation. An application for patent term extension for U. S. Patent No. 6,068,832 has already been filed by Schering Corporation based upon the same regulatory review period, requesting an extension of 926 days.

The right to a patent term extension pursuant to 35 U.S.C. § 156 is accorded to patent owners to compensate for lost patent term while the patent owner, or his agent, sought premarket approval from a regulatory agency. See Manual of Patent Examining Procedure, § 2750. Section 156(d)(1)(D) of Title 35 of the United States Code requires a description of the activities undertaken by the applicant (i.e., the patent owner or its agent) during the regulatory review period, and specifies in § 156(d)(2)(B)(i) that the lack of due diligence by the applicant during the regulatory review period may be taken into account. Given these statutory requirements, the Office has held that in order to be eligible for patent term extension, the patent owner or its agent must have undertaken the activities that led to the regulatory approval. If a patent owner has not been involved in the regulatory process, either directly or indirectly, that patent owner has not lost any effective patent life since it never invested time and resources necessary to obtain approval for commercial marketing or use. See Decision Denying Application, (United States Patent and Trademark Office Deputy Assistant Comm'r for Patent Policy and Projects Apr. 3, 1995) (concerning patent term extension application for United States Patent No. 4,631,286); aff'd, Hoechst-Roussel Pharms., Inc. v. Lehman, No. 95-650-A (E.D. Va. Oct. 27, 1995); aff'd, 109 F.3d 756, 759, 42 U.S.P.Q.2d 1220, 1223 (Fed. Cir. 1997) (Newman, C.J., concurring) (affirming on other grounds, but Judge Newman concurring in the judgment on this basis). See also Amendment to Rules for Extension of Patent Term, 60 Fed. Reg. 25615, 25616 (May 12, 1995).

The regulatory review period of DULERA® (mometasone furoate and formoterol fumarate) can

be used as a basis for extension of only one patent. See 35 U.S.C. § 156(c)(4) and 37 CFR 1.785. Since both U.S. Patent No. 6,068,832, owned by Schering Corporation and U.S. Patent No. 7,067,502 owned by Novartis AG are relying upon the premarket activities of Schering Corporation to support applications for patent term extension, the Office now requires Novartis AG to provide evidence, as set forth above, of its eligibility to apply for extension of the term of U.S. Patent No. 7,067,502 under 35 U.S.C. § 156.

Applicant is given two months to reply to this requirement. Extension of time are available under 37 CFR 1.136.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg 51, Rm. 6222
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Attn: Beverly Friedman

RE: DULERA®
Docket No.: